



DEPARTMENT OF COMMERCE

National Institutes of Standards and Technology

37 CFR Parts 401 and 404

[Docket No.: 201207-0327]

RIN 0693-AB66

Rights to Federally Funded Inventions and Licensing of Government Owned Inventions

AGENCY: National Institute of Standards and Technology (NIST), United States Department of Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The National Institute of Standards and Technology (NIST) requests comments on proposed revisions to regulations that would further the Return on Investment (ROI) Initiative for Unleashing American Innovation. The proposed revisions to “Rights to Inventions Made by Nonprofit Organizations and Small Business Firms under Government Grants, Contracts, and Cooperative Agreements” and “Licensing of Government-Owned Inventions” make technical corrections; reorganize certain subsections; remove outdated and/or unnecessary sections; institute a reporting requirement on Federal agencies; and provide clarifications on definitions, communications, scope of march-in rights, filing of provisional patent applications, electronic filing, the purpose of royalties on government licenses, and the processes for granting exclusive, co-exclusive and partially exclusive licenses and for appeals. NIST intends to hold a webinar regarding the proposed changes and information on that webinar will be available to the public at <https://www.nist.gov/tpo/bayh-dole>.

DATES:

For Comments:

Comments must be received no later than [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

For Public Webinar:

Details about accessing the public webinar will be made available via the Technology Partnerships Office web site at <http://www.nist.gov/tpo/bayh-dole>.

ADDRESSES: Submit your comments, identified by docket identification (ID) number: 201207-0327, through the *Federal e-Rulemaking Portal*: <http://www.regulations.gov> (search using the docket number). Follow the online instructions for submitting comments. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number). See SUPPLEMENTARY INFORMATION for file formats and other information about electronic filing. All submissions, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. NIST reserves the right to publish relevant comments publicly, unedited and in their entirety. Personal information, such as account numbers or Social Security numbers, or names of other individuals, should not be included. Do not submit confidential business information, or otherwise proprietary, sensitive or protected information. Comments that contain profanity, vulgarity, threats, or other inappropriate language or content will not be posted or considered.

For Public Webinar:

Details about accessing the public webinar will be made available via the Technology Partnerships Office web site at <http://www.nist.gov/tpo/bayh-dole>.

FOR FURTHER INFORMATION CONTACT: Courtney Silverthorn, via e-mail: courtney.silverthorn@nist.gov or by telephone at 301-975-4189.

SUPPLEMENTARY INFORMATION:

I. General Information

Does this action apply to me?

This action may be of interest to you if you are an educational institution, company, or nonprofit organization, especially one that has received or would like to receive Federal funding for scientific research and development.

II. Statutory Framework

These proposed rule revisions are promulgated under the University and Small Business Patent Procedures Act of 1980, Public Law 96-517 (as amended), codified at title 35 of the United States Code (U.S.C.) 200 *et seq.*, commonly known as the “Bayh-Dole Act” or “Bayh-Dole,” which governs rights in inventions made with Federal assistance. The Bayh-Dole Act obligates nonprofit organizations and small business firms (“contractors”), and large businesses, as directed by Executive Order 12591, to disclose each “subject invention” (that is, each invention conceived or first actually reduced to practice in the performance of work under a funding agreement, 35 U.S.C. 201(e)) within a reasonable time after the invention becomes known to the contractor, 35 U.S.C. 202(c)(1), and permits contractors to elect, within a reasonable time after disclosure, to retain title to a subject invention, 35 U.S.C. 202(a). Under certain defined “exceptional” circumstances, Bayh-Dole permits the Government to restrict or eliminate the contractor’s right to elect to retain title, 35 U.S.C. 202(a), 202(b), and under such circumstances, rights vest in the Government.

The Secretary of Commerce has delegated to the Director of NIST the authority to promulgate implementing regulations. Regulations implementing 35 U.S.C. 200 through 204 are codified at 37 CFR Part 401, “Rights to Inventions Made by Nonprofit Organizations and Small Business Firms under Government Grants, Contracts, and Co-operative Agreements,” and apply to all Federal agencies, 37 CFR 401.1(b). These regulations govern all subject inventions under Bayh-Dole, 37 CFR 401.2(d), even if the Federal Government is not the sole source of funding for either the conception or the reduction to practice, 37 CFR 401.1(a). Regulations implementing 35 U.S.C. 208, specifying the terms and conditions upon which federally owned inventions, other than inventions owned by the Tennessee

Valley Authority, may be licensed on a nonexclusive, partially exclusive, or exclusive basis, are codified at 37 CFR Part 404, “Licensing of Government Owned Inventions.”

Bayh-Dole and its implementing regulations require Federal funding agencies to employ certain “standard clauses” in funding agreements awarded to contractors, except under certain specified conditions; 37 CFR 401.3. Through these standard clauses, set forth at 37 CFR 401.14(a), contractors are obligated to take certain actions to properly manage subject inventions. These actions include disclosing each subject invention to the Federal agency within two months after the contractor’s inventor discloses it in writing to contractor personnel responsible for patent matters, 37 CFR 401.14(c)(1); electing in writing whether or not to retain title to any subject invention by notifying the Federal agency within two years of disclosure, 37 CFR 401.14(c)(2); filing an initial patent application on a subject invention as to which the contractor elects to retain title within one year after election, 37 CFR 401.14(c)(3); executing and promptly delivering to the Federal agency all instruments necessary to establish or confirm the rights the Government has throughout the world in those subject inventions to which the contractor elects to retain title, 37 CFR 401.14(f)(1); requiring, by written agreement, the contractor’s employees to disclose promptly in writing each subject invention made under contract, 37 CFR 401.14(f)(2); notifying the Federal agency of any decision not to continue the prosecution of a patent application, 37 CFR 401.14(f)(3); and including in the specification of any U.S. patent applications and any patent issuing thereon covering a subject invention, a statement that the invention was made with Government support under the grant or contract awarded by the Federal agency, and that the Government has certain rights in the invention, 37 CFR 401.14(f)(4).

In addition, a contractor is obligated to include the requirements of the standard clauses in any subcontracts under the contractor’s award, 37 CFR 401.14(g); to submit periodic reports as requested on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the contractor or its licensees or assignees, 37 CFR 401.14(h); and to agree that neither the contractor nor

any assignee will grant to any person the exclusive right to use or sell any subject inventions in the United States unless such person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States, 37 CFR 401.14(i), subject to waiver.

Bayh-Dole and its implementing regulations also specify certain conditions applicable to licenses granted by Federal agencies in any federally owned invention. The implementing regulations include 37 CFR 404.5, which sets forth restrictions and conditions applicable to all Federal agency licenses, 37 CFR 404.6, which addresses requirements pertaining to nonexclusive licenses, and 37 CFR 404.7, which addresses requirements pertaining to exclusive and partially exclusive licenses.

Pursuant to authority delegated to it by the Secretary of Commerce, NIST is providing notice to the public of a proposed rulemaking to revise Parts 401 and 404 of Title 37 of the Code of Federal Regulations which address rights to inventions made under Government grants, contracts, and cooperative agreements, and licensing of government owned inventions. NIST is seeking public comments on the proposed amendments. Brief explanations of the proposed changes are included below; the full text of 37 CFR Part 401 is available at <https://www.gpo.gov/fdsys/pkg/CFR-2010-title37-vol1/pdf/CFR-2010-title37-vol1-part401.pdf> and the full text of 37 CFR Part 404 is available at <https://www.gpo.gov/fdsys/granule/CFR-2004-title37-vol1/CFR-2004-title37-vol1-part404>.

III. Return on Investment Initiative

In 2018, NIST undertook a large-scale stakeholder engagement effort to inform the development of the Lab-to-Market Cross Agency Priority (CAP) goal, part of the 2018 President's Management Agenda. The Lab-to-Market CAP goal's stated purpose is to "...improve the transition of federally funded innovations from the laboratory to the marketplace by reducing the administrative and regulatory burdens for technology transfer and increasing private sector investment in later-stage research and

development (R&D); develop and implement more effective partnering models and technology transfer mechanisms for Federal agencies; and enhance the effectiveness of technology transfer by improving the methods for evaluating the ROI and economic and national security impacts of federally funded R&D, and using that information to focus efforts on approaches proven to work.”

Beginning in April 2018, NIST utilized a number of avenues to seek input from the public on ways to improve federal technology transfer and the commercialization of federally funded inventions. These included a Request for Information that NIST published in the Federal Register,¹ four public meetings,² a summit hosted by NIST, extensive consultations with interagency working groups responsible for technology transfer issues, and multiple stakeholder engagement sessions. These public inputs, as well as an extensive literature review of government and academic publications on federal technology transfer, ultimately informed NIST Special Publication 1234: Return on Investment Initiative to Advance the President’s Management Agenda, Final Green Paper.

The Green Paper described 15 findings from NIST’s stakeholder engagement process that may have the potential to “unleash American innovation” and advance the goals of Lab-to-Market through regulatory or legislative changes, updates to policy and guidance, and the development of new tools and services. In addition to the overall Lab-to-Market strategy to “Identify regulatory impediments and administrative improvements in Federal technology transfer policies and practices” (which supports the Administration’s stated goal to streamline and reduce regulatory burdens), seven of the Green Paper’s 15 findings noted potential changes to the Bayh-Dole implementing regulations that could improve compliance, enhance a contractor’s ability to commercialize subject inventions, and increase the return

¹ “Request for Information Regarding Federal Technology Transfer Authorities and Process” published in the Federal Register on May 1, 2018 (83 FR 19052).

² San Jose, California, May 17, 2018; Denver, Colorado, May 21, 2018; Oak Lawn, Illinois, May 29, 2018; NIST Campus Gaithersburg, Maryland, June 14, 2018.

on investment of Federal funding through new goods and services to the public. Four of those seven findings are considered in this notice of proposed rulemaking (NPRM or proposed rule).

As part of the overall streamlining effort in this proposed rule, some outdated or redundant text has been proposed for removal. This includes §§ 401.1(a), 401.1(c), 401.1(d), 401.1(f), 401.3(g), 401.8, 401.11(a), 401.11(b)(5), 401.13(b) and 404.4. Other text has been moved or substantially reincorporated into new sections in the proposed rule as follows: § 401.5(f) moved to § 401.14(c)(1) and (3); §§ 401.7 and 401.14(m) incorporated into §§ 401.14(k)(4) through (6); § 401.13(a) moved to § 401.14(c)(6); § 401.15 incorporated into § 401.9; § 401.16 moved to § 401.14(m); § 404.2 incorporated into § 404.1(b); and § 404.4 incorporated into § 404.5(g).

In addition to these changes and technical corrections throughout the regulation, the proposed revisions to 37 CFR Part 401 will:

- 1) Clarify in § 401.1 the scope of the regulation and applicability to large businesses unless otherwise directed by statute, and remove the outdated requirement for multiple copies of agency regulations to be submitted to the Secretary prior to OMB review.
- 2) Update the definitions of *electronically filed* and *electronic system* in § 401.2(k) and (l) to remove outdated references to “optical electronic system”.
- 3) Update the definitions of *patent application* and *initial patent application* in § 401.2(m) and (n) to encompass US provisional and non-provisional applications, applications filed in a foreign country or international patent office directly, PCT applications, and applications for Plant Variety Protection certificates.
- 4) Update § 401.5(a) to reflect that modifications to paragraph § 401.14(g) are no longer needed due to the applicability of 37 CFR Part 401 to all businesses regardless of size pursuant to EO 12591.

- 5) Revise § 401.5(b) for clarity by removing the ambiguity of “instructions” to the agency versus “instructions” to the contractor.
- 6) Revise the existing text at § 401.6(b) [new § 401.6(a)(1)] to clarify the informal agency consultation process with the contractor prior to the exercise of march-in rights, and increase the allowable time frame an agency has to respond to the contractor following the informal consultation from 60 days to 120 days.
- 7) Clarify § 401.6 to include a provision that march-in rights shall not be exercised by an agency exclusively on the basis of business decisions of a contractor regarding the pricing of commercial goods and services arising from the practical application of the invention.
- 8) Revise § 401.9 to clarify the statutory authority and process for assigning rights to an employee/inventor, and to clarify said employee/inventor’s responsibilities under 37 CFR Part 401 when receiving an assignment of rights to a subject invention made under a funding agreement, and incorporate streamlined text from § 401.15 to clarify the process by which a contractor may make a request for greater rights in an invention when the funding agreement contains an alternate provision in accordance with §401.3(a)(2), and remove the requirement for an agency to reimburse the contractor for the costs of filing a patent application while a greater rights request is under review.
- 9) Revise § 401.13 to streamline the text and clarify the confidentiality of contractor submissions made under § 401.14(c) as it relates to Freedom of Information Act requests, copies of documents filed with a patent office, and agency policies on public dissemination of results supported by agency funding programs.
- 10) Revise § 401.14(c)(3) to clarify the procedures for filing more than one provisional patent application on a disclosed subject invention.
- 11) Revise § 401.14(d) to add a new paragraph permitting agencies, at their discretion, to release the contractor from the requirement to waive title to the agency after one of the conditions in § 401.14(d) has occurred.

12) Revise § 401.14(k) to streamline the requirements for small business considerations into a single section by incorporating language from §§ 401.7 and 401.14(m).

13) Move the electronic filing requirements from § 401.16 into the standard clause at § 401.14; update the requirements to include that if the patent information and periodic reports in § 401.14(c)(3) and/or the close-out report § 401.14(c)(1) are required by an agency, they will be electronically filed unless otherwise directed by the agency; and permit other written notices to be electronically transmitted between the contractor and the agency.

14) Implement a requirement [new §401.16] for federal agencies to report annually on activities under 37 CFR Part 401, including the number of subject inventions reported, the number of patent applications filed on reported subject inventions, the number of issued patents on subject inventions, the number of requests made and granted for extensions of time under § 401.14(c)(5), the number of subject inventions to which title has been conveyed to the Government, the number of requests made and granted for a waiver of the preference for US industry requirement, and the number of requests for assignment of invention rights.

15) Remove the telephone number for the Interagency Edison service center so that contact information can be updated in a timelier fashion via the iEdison website.

This proposed rulemaking does not address government assignment to contractor of rights in invention of government employee (§ 401.10) or licensing of background rights to third parties (§ 401.12).

In addition to the aforementioned streamlining changes and technical corrections throughout the regulation, the proposed revisions to 37 CFR Part 404 will:

1) Revise § 404.1 to clarify that licensing royalties are not considered an augmentation of appropriated funds.

- 2) Revise § 404.2 to clarify the link between establishing patent license financial terms and the goal of promoting commercial use, by noting that the government may consider licensing payments as a means to ensure commercialization by the licensee and thus promote the practical application of a subject invention.
- 3) Streamline § 404.7 by removing duplicative sections and revising the paragraph to align the process for granting exclusive, co-exclusive and partially exclusive licenses with the requirements of 35 U.S.C. 209 as it pertains to the required information and publication site for a notice of intent to grant an exclusive license, the requirement to consider the interests of the Federal Government or United States industry in foreign commerce before granting an exclusive license on a foreign patent application or patent, and the additional provisions that apply to exclusive licenses beyond the requirements of § 404.5.
- 4) Revise § 404.10 to remove the requirement that a Federal agency notify sublicensees of an intent to modify or terminate a license.
- 5) Revise § 404.11 to clarify who has standing to appeal the grant, denial, modification, or termination of a license by limiting a claim of damage by the agency's granting of an exclusive license to that which denies a party the opportunity to promote the commercialization of an invention, and by requiring all agencies to establish procedures for considering appeals.

This proposed rulemaking does not address definitions (§ 404.3), nonexclusive licenses (§ 404.6), application for a license (§ 404.8), protection and administration of inventions (§ 404.12), or transfer of custody (§ 404.13).

IV. Request for Comments

NIST is requesting comments about 37 CFR Parts 401 and 404 of the Bayh-Dole regulations. We have included some questions that you might consider as you develop your comments:

1. Are there any changes to these regulations, consistent with current law, that you or your organization think would accelerate the transfer of federally funded research and technology to entrepreneurs, or otherwise strengthen the Nation's innovation system?
2. Are there specific revisions to the language in § 401.14(b) that could help clarify the existing scope of the Government Use License for owners and licensees working to achieve practical application of subject inventions?
3. Are there provisions within 37 CFR Part 401 or 404 that are inconsistent with, or otherwise affected by, changes in the patent laws under the Leahy-Smith America Invents Act, Public Law 112-29, or that Act's implementing regulations?

When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Please organize your comments by referencing the specific question you are responding to or the relevant section number in the proposed regulatory text.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. Provide specific examples to illustrate your concerns and suggest alternatives.
- vi. Explain your views as clearly as possible.
- vii. All submissions, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. NIST reserves the right to publish relevant comments publicly, unedited and in their entirety. Personal information, such as account numbers or Social Security numbers, or names of other individuals, should not be included. Do not submit confidential business information, or otherwise proprietary, sensitive or protected information. Comments that contain profanity, vulgarity, threats, or other inappropriate language will not be considered.
- viii. Make sure to submit your comments by the comment period deadline identified.

ix. The following formats are preferred for comment submissions: .doc or .docx, .pdf, and .txt.

V. References

1. National Institute of Standards and Technology (2019). *Unleashing American Innovation: Return on Investment Initiative to Advance the President's Management Agenda, Final Green Paper*. NIST Special Publication 1234, retrieved from: <https://www.nist.gov/unleashing-american-innovation/green-paper>.
2. Copan, W. and Kratsios, M. (2019). *Lab to Market: Cross Agency Priority Goal Quarterly Progress Update, December 2019*. Retrieved from: https://www.performance.gov/CAP/action_plans/dec_2019_Lab_to_Market.pdf.
3. *Additional Actions Needed to Improve Licensing of Patented Laboratory Inventions*. (2018). GAO-18-327, Retrieved from: <https://www.gao.gov/assets/700/692961.pdf>.
4. National Institute of Standards and Technology (2019). *Federal Laboratory Technology Transfer, Fiscal Year 2016 Summary Report to the President and the Congress*. Retrieved from: <https://www.nist.gov/tpo/reports-and-publications>. See “Federal Licenses” table on page 8.
5. Federal Laboratory Consortium for Technology Transfer. (2013). *Technology Transfer Desk Reference*. Retrieved from: <https://federallabs.org/media/publication-library/flc-technology-transfer-desk-reference>.

VI. Statutory and Executive Order Reviews

Executive Order 12866

This rulemaking is a significant regulatory action under Executive Order 12866. This rulemaking, however, is not an “economically significant” regulatory action under section 3(f)(1) of the Executive order, as it does not have an effect on the economy of \$100 million or more in any one year, and it does not have a material adverse effect on the economy, a sector of the economy,

productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

Executive Order 13132

This proposed rule does not contain policies with federalism implications as defined in Executive Order 13132.

Executive Order 13771

This final rule is considered to be an EO 13771 deregulatory action. The proposed regulation is deregulatory in that it is removing duplicative text and streamlining and/or reducing regulatory burdens, all at no additional cost.

The proposed regulation: (1) Updates the definitions of *patent application* and *initial patent application* in § 401.2(m) and (n) to encompass US provisional and non-provisional applications, applications filed in a foreign country or international patent office directly, PCT applications, and applications for Plant Variety Protection certificates, which reduces patent filing burdens for recipients of federal funding by providing additional options to fulfill the regulation's filing requirements. (2) Clarifies § 401.6 to include a provision that march-in rights shall not be exercised by an agency exclusively on the basis of business decisions of a contractor regarding the pricing of commercial goods and services arising from practical application of the invention, which limits the government's use of this provision and provides additional certainty to licensees. (3) Moves the electronic filing requirements from § 401.16 into the standard clause at § 401.14; update the requirements to include that if the patent information and periodic reports in § 401.14(c)(3) and/or the close-out report § 401.14(c)(1) are required by an agency, they will be electronically filed unless otherwise directed by the agency; and permit other written notices to be electronically transmitted between the contractor and the agency, which reduces the burden on recipients of federal funding to complete and submit paper forms.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires the preparation and availability for public comment of "an initial regulatory flexibility analysis" which will "describe the impact of the proposed rule on small

entities.” (5 U.S.C. 603(a)). Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the proposed rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration (SBA) that this rulemaking, if adopted, would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination is as follows:

A description of this proposed rule, why it is being considered, and the objectives of this proposed rule are contained in the preamble and in the **SUMMARY** section of the preamble. The statutory basis for this proposed rule is provided by 35 U.S.C. 200-212. The Bayh-Dole Act and its implementing regulations apply to all small business firms and nonprofit organizations that have entered into a Federal funding agreement, as defined in 35 U.S.C. 201, and express a policy to “encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; [and] to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery.” 35 U.S.C. 200. For small business firms and nonprofit organizations that deal with the Government in areas of technology development, the Bayh-Dole implementing regulations make it easier to participate in federally-supported programs by guaranteeing the protection of the intellectual property they create. This proposed rule, if implemented, would predominantly make technical changes and clarifications, remove outdated material, and streamline the regulation, and is not anticipated to have any quantifiable economic impact with respect to small entities. Several proposed changes would reduce administrative burdens and increase the ability of small entities to fulfill regulatory requirements through electronic submissions, while clarifying the confidentiality of said submissions so as to not affect the ability to seek patent protection on a subject invention. The proposed change to the definition of an “initial patent application” expands the applications by which a contractor can fulfil the filing

requirement of the regulation, providing additional flexibility for small entities. Proposed revisions to 37 CFR 401.6 provide additional clarity on the scope of the Government's march-in rights, while the proposed revision to 37 CFR 401.14(d) provides an avenue for an agency to release a small entity from the requirement to convey title to the Government if they have taken corrective actions after failing to meet a regulatory requirement – these revisions will all increase the ability for a small entity to more effectively attract outside funding for their inventions. Proposed revisions to 37 CFR 401.9 and § 401.15 will clarify the process by which small entities and sole proprietors may request title to their inventions when not otherwise automatically granted title by the funding agreement. While the requirements for small business considerations in licensing have been significantly streamlined, the proposed revision greatly increases the clarity of these requirements while not affecting any of the statutory requirements that a contractor must fulfill with regard to small entities. Finally, revisions to 37 CFR 404.7 will make it easier for small entities to seek exclusive, co-exclusive, or partially exclusive licenses.

The information provided above supports a determination that this proposed rule would not have a significant economic impact on a substantial number of small entities. Because this rulemaking, if implemented, is not expected to have a significant economic impact on any small entities, an initial regulatory flexibility analysis is not required and none has been prepared.

Paperwork Reduction Act

This proposed rule contains no new collection of information subject to the Paperwork Reduction Act, 44 U.S.C. 3501 et seq.

National Environmental Policy Act

This proposed rule will not significantly affect the quality of the human environment. Therefore, an environmental assessment or Environmental Impact Statement is not required to be prepared under the National Environmental Policy Act of 1969.

List of Subjects in 37 CFR Parts 401 and 404

Inventions and patents, Laboratories, Research and development, Science and technology, Technology transfer.

For the reasons stated in the preamble, the National Institute of Standards and Technology proposes to amend 37 CFR parts 401 and 404 as follows:

PART 401 - RIGHTS TO INVENTIONS MADE BY NONPROFIT ORGANIZATIONS AND SMALL BUSINESS FIRMS UNDER GOVERNMENT GRANTS, CONTRACTS, AND COOPERATIVE AGREEMENTS

1. The authority citation for 37 CFR part 401 continues to read as follows:

Authority: 35 U.S.C. 206; DDO 30-2A.

2. Revise § 401.1 to read as follows:

§ 401.1 Scope.

- (a) This part implements 35 U.S.C. 200 through 204 and is applicable to any funding agreement with a nonprofit organization or small business firm as defined by 35 USC 201, except for an agreement made primarily for educational purposes under 35 U.S.C. 212. This part also applies to any funding agreement with business firms regardless of size in accordance with section 1, paragraph (b)(4) of Executive Order 12591, as amended by Executive Order 12618, unless directed otherwise pursuant to NASA or DOE vesting statutes.
- (b) This regulation supersedes OMB Circular A-124 and shall take precedence over any regulations or other guidance dealing with ownership of inventions made by businesses and nonprofit organizations which are inconsistent with it. Only deviations requested by a contractor and not inconsistent with Chapter 18 of Title 35, United States Code, may be made without approval of the Secretary. Modifications or tailoring of clauses as

authorized by § 401.5 or 401.3, when alternate provisions are used under § 401.3(a)(1) through (6), are not considered deviations requiring the Secretary's approval.

- (c) This part is not intended to apply to arrangements under which nonprofit organizations, small business firms, or others are allowed to use government-owned research facilities and normal technical assistance provided to users of those facilities, whether on a reimbursable or nonreimbursable basis. This part is also not intended to apply to arrangements under which sponsors reimburse the government or facility contractor for the contractor employee's time in performing work for the sponsor. Such arrangements are not considered “funding agreements” as defined at 35 U.S.C. 201(b) and § 401.2(a).

3. Amend § 401.2 by revising the introductory text and paragraphs (k) through (o) to read as follows:

§ 401.2 Definitions.

In addition to the definitions in 35 U.S.C. 201, as used in this part—

* * * * *

- (k) The term *electronically filed* means any submission of information transmitted by an electronic system.
- (l) The term *electronic system* means a software-based system approved by the agency for the transmission of information.
- (m) The term *patent application* or “application for patent” may be the following:
- (1) A United States provisional application as defined in 37 CFR 1.9(a)(2) and filed under 35 U.S.C. 111(b); or
- (2) A United States nonprovisional application as defined in 37 CFR 1.9(a)(3) and filed under 35 U.S.C. 111(a); or
- (3) A patent application filed in a foreign country or an international patent office; or
- (4) A patent application filed under the Patent Cooperation Treaty as defined in 37 CFR 1.9(b) which designates the United States; or

(5) An application for a Plant Variety Protection certificate.

(n) The term *initial patent application* means, as to a given subject invention:

(1) The first United States provisional application as defined in 37 CFR 1.9(a)(2) and filed under 35 U.S.C. 111(b); or

(2) The first United States nonprovisional application as defined in 37 CFR 1.9(a)(3) and filed under 35 U.S.C. 111(a); or

(3) The first patent application filed in a foreign country or an international patent office; or

(4) The first patent application filed under the Patent Cooperation Treaty as defined in 37 CFR 1.9(b) which designates the United States; or

(5) The first application for a Plant Variety Protection certificate.

(o) The term *statutory period* means the one-year period before the effective filing date of a claimed invention in a patent application during which exceptions to prior art exist per 35 U.S.C. 102(b) as amended by the Leahy-Smith America Invents Act, Public Law 112-29.

§ 401.3 [Amended]

4. Amend § 401.3 as follows:

- a. Remove “§ 401.5(g)” and add in its place “§ 401.5(f)” in paragraph (c)(3);
- b. Remove “of Commerce” from the fourth sentence of paragraph (f); and
- c. Remove paragraph (g) and redesignate paragraphs (h) and (i) as paragraphs (g) and (h).

§ 401.4 [Amended]

5. Amend § 401.4 as follows:

- a. Remove “35 U.S.C. 202(b)(4)” and add in its place “35 U.S.C. 202(b)(3)” in the first sentence of paragraph (a); and
- b. Remove “United States Claims Court” and add in its place “United States Court of Federal Claims” in the last sentence of paragraph (b)(6).

6. Amend § 401.5 as follows:

- a. Revise paragraphs (a) and (b);

- b. Remove paragraph (f) and redesignate paragraphs (g) and (h) as paragraphs (f) and (g);
- c. Revise the newly redesignated paragraph (g).

The revisions read as follows:

§ 401.5 Modification and tailoring of clauses.

- (a) Agencies should complete the blank in paragraph (g)(2) of the clauses at § 401.14 in accordance with their own or applicable government-wide regulations such as the Federal Acquisition Regulation. If the funding agreement is a grant or cooperative agreement, paragraph (g)(3) of the clause may be deleted.
- (b) Agencies should complete paragraph (l) of the clause in § 401.14, “Communication” by designating a central point of contact for communications on matters relating to the clause. Agencies may also include additional information on communications in paragraph (l) of the clause in § 401.14.

* * * * *

- (g) If the contract is for the operation of a government-owned facility, agencies may add paragraph (f)(6) to the clause at § 401.14 with the following text:

The contractor shall establish and maintain active and effective procedures to ensure that subject inventions are promptly identified and timely disclosed and shall submit a description of the procedures to the *contracting officer* so that the *contracting officer* may evaluate and determine their effectiveness.

7. Amend § 401.6 as follows:

- a. Remove the period from the end of paragraph (a) introductory text and add in its place a colon;
- b. Add paragraphs (a)(1) through (7);
- c. Redesignate paragraph (b) as paragraph (a)(1) and revise the newly redesignated paragraph (a)(1);
- d. Redesignate paragraphs (c) and (d) as paragraphs (a)(2) and (3);
- e. Redesignate paragraph (e) as paragraph (a)(4) and revise the newly redesignated paragraph (a)(4);

- f. Redesignate paragraphs (f) through (h) as paragraphs (a)(5) through (7) respectively;
- g. Redesignate paragraph (i) as paragraph (b);
- h. Redesignate paragraph (j) as paragraph (c) and revise the newly redesignated paragraph (c);
- i. Redesignate paragraph (k) as paragraph (d);
- j. Add a new paragraph (e);
- k. Redesignate paragraph (l) as paragraph (f).

The revisions and additions read as follows:

§ 401.6 Exercise of march-in rights.

(a) * * *

- (1) Whenever an agency receives information that it believes might warrant the exercise of march-in rights, before initiating any march-in proceeding, it shall notify the contractor in writing (including electronic means) of the information and request an informal consultation and information relevant to the matter with the contractor to understand the nature of the issue and consider possible actions other than exercising march-in rights. In the absence of response from the contractor to the agency request for informal consultation within 30 days, the agency may, at its discretion, proceed with the procedures below. If informal consultation occurs within 30 days, or later if the agency has not initiated the procedures below, then the agency shall, within 120 days after informal consultation, either notify the contractor of the initiation of the procedures below with a summary of the efforts taken, or notify the contractor, in writing, that it will not pursue march-in rights on the basis of the available information.
- (2) A march-in proceeding shall be initiated by the issuance of a written notice by the agency to the contractor and its assignee or exclusive licensee, as applicable and if known to the agency, stating that the agency is considering the exercise of march-in

rights. The notice shall state the reasons for the proposed march-in in terms sufficient to put the contractor on notice of the facts upon which the action would be based and shall specify the field or fields of use in which the agency is considering requiring licensing. The notice shall advise the contractor (assignee or exclusive licensee) of its rights, as set forth in this section and in any supplemental agency regulations. The determination to exercise march-in rights shall be made by the head of the agency or his or her designee.

- (3) Within 30 days after the receipt of the written notice of march-in, the contractor (assignee or exclusive licensee) may submit in person, in writing, or through a representative, information or argument in opposition to the proposed march-in, including any additional specific information which raises a genuine dispute over the material facts upon which the march-in is based. If the information presented raises a genuine dispute over the material facts, the head of the agency or designee shall undertake or refer the matter to another official for fact-finding.
- (4) Fact-finding shall be conducted in accordance with the procedures established by the agency. Such procedures shall be as informal as practicable and be consistent with principles of fundamental fairness. The procedures should afford the contractor the opportunity to appear with counsel, submit documentary evidence, present witnesses and confront such persons as the agency may present. A transcribed record shall be made and shall be available at cost to the contractor upon request. The requirement for a transcribed record may be waived by mutual agreement of the contractor and the agency. Any portion of the march-in proceeding, including a fact-finding hearing that involves testimony or evidence relating to the utilization or efforts at obtaining utilization that are being made by the contractor, its assignee, or licensees shall be closed to the public, including potential licensees. In accordance with 35 U.S.C. 202(c)(5), agencies shall not disclose any such information obtained during a march-

in proceeding to persons outside the government except when such release is authorized by the contractor (assignee or licensee) or otherwise required by law.

- (5) The official conducting the fact-finding shall prepare or adopt written findings of fact and transmit them to the head of the agency or designee promptly after the conclusion of the fact-finding proceeding along with a recommended determination. A copy of the findings of fact shall be sent to the contractor (assignee or exclusive licensee) by registered or certified mail. The contractor (assignee or exclusive licensee) and agency representatives will be given 30 days to submit written arguments to the head of the agency or designee; and, upon request by the contractor oral arguments will be held before the agency head or designee that will make the final determination.
- (6) In cases in which fact-finding has been conducted, the head of the agency or designee shall base his or her determination on the facts found, together with any other information and written or oral arguments submitted by the contractor (assignee or exclusive licensee) and agency representatives, and any other information in the administrative record. The consistency of the exercise of march-in rights with the policy and objectives of 35 U.S.C. 200 shall also be considered. In cases referred for fact-finding, the head of the agency or designee may reject only those facts that have been found to be clearly erroneous, but must explicitly state the rejection and indicate the basis for the contrary finding. Written notice of the determination whether march-in rights will be exercised shall be made by the head of the agency or designee and sent to the contractor (assignee or exclusive licensee) by certified or registered mail within 90 days after the completion of fact-finding or 90 days after oral arguments, whichever is later, or the proceedings will be deemed to have been terminated and thereafter no march-in based on the facts and reasons upon which the proceeding was initiated may be exercised.

- (7) An agency may, at any time, terminate a march-in proceeding if it is satisfied that it does not wish to exercise march-in rights.
- (b) The procedures of this part shall also apply to the exercise of march-in rights against inventors receiving title to subject inventions under 35 U.S.C. 202(d) and, for that purpose, the term “contractor” as used in this section shall be deemed to include the inventor.
- (c) An agency determination unfavorable to the contractor (assignee or exclusive licensee) shall be held in abeyance pending the exhaustion of appeals or petitions filed under 35 U.S.C. 203(b).
- (d) For purposes of this section the term exclusive licensee includes a partially exclusive licensee.
- (e) March-in rights shall not be exercised exclusively based on the business decisions of the contractor regarding the pricing of commercial goods and services arising from the practical application of the invention.
- (f) Agencies are authorized to issue supplemental procedures not inconsistent with this part for the conduct of march-in proceedings.

§§ 401.7 and 401.8 [Removed and Reserved]

8. Remove and reserve §§ 401.7 and 401.8.

9. Revise § 401.9 as follows:

§ 401.9 Contractor and contractor employee inventor requests for rights in inventions.

- (a) Agencies shall allow a contractor to request greater rights in an invention, including a request to return title to an invention to the contractor, when the funding agreement contains alternate provisions in accordance with § 401.3(a)(2):
- (1) The agency shall consider if the circumstances which originally led the agency to invoke an exception under § 401.3(a) are currently valid and applicable to the actual subject invention.

- (i) The agency shall provide the contractor the opportunity to submit information on its plans and intentions to bring the subject invention to practical application pursuant to 35 U.S.C. 200.
 - (ii) The agency shall assess whether government ownership of the invention will better promote the policies and objectives of 35 U.S.C. 200 than the plans and intentions submitted by the contractor.
 - (iii) The agency shall consider whether to allow the standard clause at § 401.14 to apply with additional conditions imposed upon the contractor's use of the invention for specific uses or applications, or with expanded government license rights in such uses or applications.
- (2) The agency shall reply to the contractor with its determination within 90 days after receiving a request and any supporting information from the contractor. If a bar to patenting is sooner than 90 days from receipt of a request, the agency may either file a patent application on the subject invention or authorize the contractor to file a patent application at its own risk and expense.
- (3) The Department of Energy is authorized to process deferred determinations either in accordance with its waiver regulations or this section.
- (b) Pursuant to 35 U.S.C. 202(d), a contractor is required to obtain approval from a funding Agency before assigning rights to a subject invention made under a funding agreement to an employee/inventor. When an employee/inventor retains rights to a subject invention made under a funding agreement, either the Agency or the contractor must ensure compliance by the employee/inventor with at least those conditions that would apply under paragraphs (b), (d), (f)(4), (h), (i), and (j) of the clause at § 401.14.

10. Amend § 401.11 as follows:

- a. Remove paragraph (a);
- b. Redesignate paragraph (b) as paragraph (a);

- c. Revise the newly redesignated paragraphs (a)(1) through (4);
- d. Remove newly redesignated paragraph (a)(5);
- e. Redesignate paragraphs (c) through (e) as paragraphs (b) through (d), respectively, and revise the newly redesignated paragraphs (b) through (d).

The revisions read as follows:

§ 401.11 Appeals.

(a) * * *

(1) A refusal to grant an extension under paragraph (c)(5) of the standard clause at § 401.14.

(2) A request for a conveyance of title under paragraph (d)(1) of the standard clause at § 401.14.

(3) A refusal to grant a waiver under paragraph (i) of the standard clause at § 401.14.

(4) A refusal to approve an assignment under paragraph (k)(1) of the standard clause at § 401.14.

(b) Each agency shall establish and publish procedures under which any of the agency actions listed in paragraph (a) of this section may be appealed to the head of the agency or designee. Review at this level shall consider both the factual and legal basis for the actions and its consistency with the policy and objectives of 35 U.S.C. 200-206.

(c) Appeals procedures established under paragraph (b) of this section shall include administrative due process procedures and standards for fact-finding at least comparable to those set forth in § 401.6(a)(4) through (6) whenever there is a dispute as to the factual basis for an agency request for a conveyance of title under paragraph (d) of the standard clause at § 401.14, including any dispute as to whether or not an invention is a subject invention.

- (d) To the extent that any of the actions described in paragraph (a) of this section are subject to appeal under the Contract Dispute Act, the procedures under the Act will satisfy the requirements of paragraphs (b) and (c) of this section.

11. Revise § 401.13 to read as follows:

§ 401.13 Confidentiality of contractor submissions.

Pursuant to 35 U.S.C. 202(c)(5) and 205, the following procedures shall govern confidentiality of documents submitted under paragraph (c) of the standard clause found at § 401.14:

- (a) Agencies shall not disclose to third parties pursuant to requests under the Freedom of Information Act (FOIA) any information disclosing a subject invention during the time which an initial patent application may be filed under paragraph (c) of the standard clause found at § 401.14 or such other clause in the funding agreement. This prohibition does not apply to information that has previously been published by the inventor, contractor, or otherwise.
- (b) Agencies shall not disclose or release, pursuant to requests under the Freedom of Information Act or otherwise, copies of any document which is part of an application for patent with the U.S. Patent and Trademark Office or any foreign patent office filed by the contractor (or its assignees, licensees, or employees) on a subject invention to which the contractor has elected to retain title. This prohibition does not extend to disclosure to other government agencies or contractors of government agencies under an obligation to maintain such information in confidence. This prohibition does not apply to documents published by the U.S. Patent and Trademark Office or any foreign patent office.
- (c) When implementing policies that encourage public dissemination of the results of work supported by the agency through government publications or other publications of technical reports, agencies shall not include copies of documents submitted by contractors pursuant to § 401.14(c) when a contractor notifies the agency that a particular

report or other submission contains a disclosure of a subject invention to which it has elected title or may elect title, or such publication could create a statutory bar to obtaining patent protection.

12. Amend § 401.14 as follows:

- a. Revise paragraphs (a)(2) and (7), and (c)(1) and (3);
- b. Add paragraph (c)(6);
- c. Revise paragraph (d);
- d. Remove “sucessor” and add in its place “successor” in the final sentence of paragraph (e)(1);
- e. Revise paragraph (f)(3);
- f. Remove “incidental” and add in its place “incidental” in paragraph (k)(3);
- g. Revise paragraph (k)(4);
- h. Add paragraphs (k)(5) and (6);
- i. Add paragraph (m).

The revisions read as follows:

§ 401.14 Standard patent rights clauses.

* * * * *

(a) * * *

(2) *Subject invention* means any invention of a contractor conceived or first actually reduced to practice in the performance of work under a funding agreement; provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of contract performance. An invention that is conceived and reduced to practice without the use of any federal funds is not considered a subject invention.

* * * * *

(7) The term *statutory period* means the one-year period before the effective filing date of a claimed invention in a patent application during which exceptions to prior art exist per 35 U.S.C. 102(b) as amended by the Leahy-Smith America Invents Act, Public Law 112-29.

* * * * *

(c) * * *

(1) The *contractor* will disclose each subject invention to the *Federal agency* within two months after the inventor discloses it in writing to contractor personnel responsible for patent matters. The disclosure to the agency shall be in the form of a written report and shall identify the contract under which the invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale or public use of the invention, and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to the agency, the *contractor* will promptly notify the agency of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the contractor. If required by the *Federal agency*, the *contractor* will provide periodic (but no more frequently than annual) listings of all subject inventions which were disclosed to the agency during the period covered by the report, and will provide a report prior to the close-out of a funding agreement listing all subject inventions or stating that there were none.

* * * * *

(3) (i) The *contractor* will file its initial patent application on a subject invention to which it elects to retain title within one year after election of title or, if earlier, prior to the end of any statutory period wherein valid patent protection can be obtained in the United States after a publication, on sale, or public use. Subject to the grant of an extension by an agency under

paragraph (c)(5) of this clause, if the contractor files a provisional application as its initial patent application, it shall file a non-provisional application within 10 months of the filing of the provisional application.

(ii) Each provisional application filed following the initial patent application must contain additional written description of the subject invention not previously disclosed in a patent application. The *contractor* shall file or notify the government that they do not intend to file a non-provisional application within 10 months of the last filed provisional application that is consistent with this section.

(iii) The *contractor* will file patent applications in additional countries or international patent offices within either ten months of the first filed patent application or six months from the date permission is granted by the Commissioner of Patents to file foreign patent applications where such filing has been prohibited by a Secrecy Order.

(iv) If required by the *Federal agency*, the *contractor* will provide the filing date, patent application number and title; a copy of the patent application; and patent number and issue date for any subject invention in any country in which the contractor has applied for a patent.

* * * * *

(6) In the event a subject invention is made under funding agreements of more than one agency, at the request of the *contractor* or on their own initiative the agencies shall designate one agency as responsible for administration of the rights of the government in the invention.

(d) Conditions When the Government May Obtain Title

(1) A *Federal agency* may require the *contractor* to convey title to the *Federal agency* of any subject invention—

(i) If the *contractor* fails to disclose or elect title to the subject invention within the times specified in paragraph (c) of this clause, or elects not to retain title.

(ii) In those countries in which the *contractor* fails to file patent applications within the times specified in paragraph (c) of this clause; provided, however, that if the contractor has filed a

patent application in a country after the times specified in paragraph (c) of this clause, but prior to its receipt of the written request of the *Federal agency*, the *contractor* shall continue to retain title in that country.

(iii) In any country in which the *contractor* decides not to continue the prosecution of any non-provisional patent application for, to pay a maintenance, annuity or renewal fee on, or to defend in a reexamination or opposition proceeding on, a patent on a subject invention.

(2) A *Federal agency*, at its discretion, may waive the requirement for the *contractor* to convey title to any subject invention.

* * * * *

(f) * * *

(3) For each subject invention, the *contractor* will, no less than 60 days prior to the expiration of the statutory deadline, or 60 days prior to the date if 401.14(c)(5) applies, notify the *Federal agency* of any decision.

* * * * *

(k) * * *

(4) It will make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business firms and that, when appropriate, it will give a preference to a small business firm when licensing a subject invention;

(5) The *Federal agency* may review the *contractor's* licensing program and decisions regarding small business applicants, and the *contractor* will negotiate changes to its licensing policies, procedures, or practices with the *Federal agency* when the *Federal agency's* review discloses that the contractor could take reasonable steps to more effectively implement the requirements of paragraph (k)(4) of this clause; and

(6) The *Federal agency* may take into consideration concerns presented by small businesses in making such determinations in paragraph (k)(5) of this clause.

* * * * *

(m) Electronic Filing

(a) Unless otherwise requested or directed by the *Federal agency*--

(1) The written disclosure required in (c)(1) of this clause shall be electronically filed;

(2) The written election required in (c)(2) of this clause shall be electronically filed; and

(3) If required by the agency to be submitted, the close-out report in paragraph (c)(1) of this clause and the patent information and periodic reporting identified in paragraph (c)(3) of this clause shall be electronically filed.

(b) Other written notices required in this clause may be electronically delivered to the agency or the *contractor* through an electronic database used for reporting subject inventions, patents, and utilization reports to the funding agency.

§ 401.15 [Removed and Reserved]

13. Remove and reserve § 401.15.

14. Revise § 401.16 to read as follows:

§ 401.16 Federal agency reporting requirements.

Federal agencies will report annually to the Secretary of Commerce on data pertaining to reported subject inventions under a funding agreement, including—

(a) Number of subject inventions reported to the Federal Agency;

(b) Patent applications filed on subject inventions;

(c) Issued patents on subject inventions;

(d) Number of requests and number of requests granted for extension of the time for disclosures, election, and filing per 37 CFR 401.14(c)(5);

(e) Number of subject inventions conveyed to the Government in accordance with 37 CFR 401.14(d);

(f) Number of waivers requested and waivers granted per 37 CFR 401.14(i); and

(g) Number of requests for assignment of invention rights. Such information will be received by the Secretary no later than the last day of October of each year.

§ 401.17 [Amended]

15. Amend § 401.17 by removing the phrase “, telephone (301) 435-1986” before the final period of the paragraph.

PART 404—LICENSING OF GOVERNMENT OWNED INVENTIONS

16. The authority citation for 37 CFR part 404 continues to read as follows:

Authority: 35 U.S.C. 207-209, DOO 30-2A.

17. Revise § 404.1 to read as follows:

§ 404.1 Scope of part.

- (a) This part prescribes the terms, conditions, and procedures upon which a federally owned invention, other than an invention in the custody of the Tennessee Valley Authority, may be licensed. This part does not affect licenses which:

- (1) Were in effect prior to April 7, 2006;
- (2) May exist at the time of the Government's acquisition of title to the invention, including those resulting from the allocation of rights to inventions made under Government research and development contracts;
- (3) Are the result of an authorized exchange of rights in the settlement of patent disputes, including interferences; or
- (4) Are otherwise authorized by law or treaty, including 35 U.S.C. 202(e), 35 U.S.C. 207(a)(3) and 15 U.S.C. 3710a, which also may authorize the assignment of inventions. Although licenses on inventions made under a cooperative research and development agreement (CRADA) are not subject to this regulation, agencies are encouraged to apply the same policies and use similar terms when appropriate. Similarly, this should be done for licenses granted under inventions where the agency has acquired rights pursuant to 35 U.S.C. 207(a)(3).

- (b) Royalties collected pursuant to this part are not intended as an alternative to appropriated funding or as an alternative funding mechanism.

18. Revise § 404.2 to read as follows:

§ 404.2 Policy and objective.

It is the policy and objective of this subpart to promote the results of federally funded research and development through the patenting and licensing process. In negotiating licenses, the Government may consider payments under a licensing agreement as a means for promoting the practical application of a subject invention and as a method to ensure commercialization by the licensee.

§ 404.4 [Removed and Reserved]

19. Remove and reserve § 404.4.

§ 404.5 [Amended]

20. Amend § 404.5 by removing “§ 404.5(a)(2)” from paragraph (b)(8)(iv) and adding in its place “35 U.S.C. 209(b)”.

21. Revise § 404.7 to read as follows:

§ 404.7 Exclusive, co-exclusive, and partially exclusive licenses.

(a) Exclusive, co-exclusive or partially exclusive licenses may be granted on Government owned inventions, only if:

(1) Notice of a prospective license, identifying the invention at a minimum, has been published and responses, if any, reviewed in accordance with 35 USC 209. The agency, in its discretion, may include other information as appropriate;

(2) After expiration of the public notice period and consideration of any written objections received in accordance with 35 USC 209(e), the Federal agency has determined that:

(i) The public will be served by the granting of the license, as indicated by the applicant's intentions, plans and ability to bring the invention to the point of practical application or otherwise promote the invention's utilization by the public;

- (ii) The proposed scope of exclusivity is not greater than reasonably necessary to provide the incentive for bringing the invention to practical application, as proposed by the applicant, or otherwise to promote the invention's utilization by the public; and
 - (iii) Exclusive, co-exclusive or partially exclusive licensing is a reasonable and necessary incentive to call forth the investment capital and expenditures needed to bring the invention to practical application or otherwise promote the invention's utilization by the public;
 - (3) The Federal agency has determined that the grant of such a license will not tend substantially to lessen competition or create or maintain a violation of the Federal antitrust laws;
 - (4) The Federal agency has given first preference to any small business firms submitting plans that are determined by the agency to be within the capability of the firms and as having equal or greater likelihood as those from other applicants to bring the invention to practical application within a reasonable time; and
 - (5) In the case of an invention covered by a foreign patent application or patent, the interests of the Federal Government or United States industry in foreign commerce will be enhanced.
- (b) In addition to the provisions of § 404.5, the following terms and conditions apply to exclusive, co-exclusive and partially exclusive licenses:
- (1) The license shall be subject to the irrevocable, royalty-free right of the Government of the United States to practice or have practiced the invention on behalf of the United States and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement with the United States.

- (2) The license shall reserve to the Federal agency the right to require the licensee to grant sublicenses to responsible applicants, on reasonable terms, when necessary to fulfill health or safety needs.
- (3) The license shall be subject to any licenses in force at the time of the grant of the exclusive, co-exclusive or partially exclusive license.
- (4) The license may grant the licensee the right to take any suitable and necessary actions to protect the licensed property, on behalf of the Federal Government.
- (c) Federal agencies shall maintain a record of determinations to grant exclusive, co-exclusive or partially exclusive licenses.

§ 404.10 [Amended]

- 22. Amend § 404.10 by removing “and any sublicensee of record”.
- 23. Revise paragraphs (a) introductory text, (a)(3), and (b) to read as follows:

§ 404.11 Appeals.

- (a) The following parties may appeal to the agency head or designee any decision or determination concerning the grant, denial, modification, or termination of a license:

* * * * *

- (3) A person who timely filed a written objection in response to the notice required by § 404.7 and who can demonstrate to the satisfaction of the Federal agency that such person may be damaged by the agency action due to being denied the opportunity to promote the commercialization of the invention.
- (b) The Federal agency shall establish appropriate procedures for considering appeals under paragraph (a) of this section.

- 24. Revise § 404.14 to read as follows:

§ 404.14 Confidentiality of information.

35 U.S.C. 209(f) requires that any plan submitted pursuant to § 404.8(a)(8) and any report required by 35 U.S.C. 209(d)(2) shall be treated as commercial or financial information

obtained from a person and privileged and confidential and not subject to disclosure under 5 U.S.C. 552.

Kevin Kimball
Chief of Staff

[FR Doc. 2020-27581 Filed: 12/31/2020 8:45 am; Publication Date: 1/4/2021]